

**REMARKS**

Claims 1-13 are pending in the application, of which all claims stand rejected solely on the basis of provisional obviousness-type double patenting rejections. Applicants respectfully submit that at least two of the provisional double patenting rejections of the August 11, 2006 Office Action are not appropriate, and request that the two rejections be withdrawn for the reasons presented below. Applicants do not address the remaining provisional rejections at this time, since Applicants are not required to respond to provisional rejections.

**REQUEST FOR WITHDRAWAL OF PROVISIONAL**  
**DOUBLE PATENTING REJECTIONS OVER 09/983,234 AND 09/026,353**

Claims 1-13 stand “provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-14, 16-19, 23-30, 32, 33, 37-50, 52-56, 84-132 of copending Application No. 09/863,234 in view of Dunn et al. (5,717,030). Dunn et al teach a system that can be implanted anywhere in the body including bone, as best seen in column 5, lines 19-22. The system can be biodegradable and the active ingredient can include bone growth agents. Therefore, Dunn teach a bone substitute material that is bioabsorbable to promote bone growth. It would have been obvious to one having ordinary skill in the art to modify the copending claims to include bone substitute material at the wound to repair bone tissue. The copending claims already recite the treatment of repairing bone tissue. Dunn et al teach the details of the material that would provide the recited function.”

Claims 1-13 stand “provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-41, 43-69, 71-80, 83-86 of copending Application No. 09/026353 in view of Dunn et al. (5,717,030). Dunn et al teach a system that can be implanted anywhere in the body including bone, as best seen in column 5, lines 19-22. The system can be biodegradable and the active ingredient can include bone growth agents. Therefore, Dunn teach a bone substitute material that is bioabsorbable to promote bone growth. It would have been obvious to one having ordinary skill in the art to modify the copending claims to include bone substitute material at the wound to repair bone tissue. The

copending claims already recite the treatment of repairing bone tissue. Dunn et al teach the details of the material that would provide the recited function.”

Applicants respectfully submit that the double patenting rejections over copending application numbers 09/863234 (`234 application) and 09/026353 (`353 application) quoted above are inappropriate in the instant case, for at least the reason that it is not obvious to modify either the `234 application or `353 application in view of Dunn. (Since a “double patenting rejection of the obviousness-type is ‘analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. 103’ ”, Applicants’ arguments against the double patenting rejecting are phrased in the analogous 103 terminology. (MPEP, p 800-21, Rev. 3, August 2005).)

Applicants’ claimed invention is directed to an apparatus and method for promoting directed tissue growth within a bone substitute material through the application of reduced pressure to the tissue to be grown. In contrast, the `234 and `353 applications, are directed to devices and treatment methods for reduced pressure therapy of soft tissues. The applications teach that *soft tissues* might be amenable to treatment by reduced pressure therapy, because *soft tissue* can contract and deform in response to the application of reduced pressure. That is, the reasons for successful treatment were postulated to be due to mechanisms that could be expected to affect soft tissue but not hard tissue to a significant degree. In this regard, the statements in the office action that the “copending claims already cite the treatment of repairing bone tissue” are mistaken. Nowhere in the copending claims of the `234 and `353 applications is the term “bone tissue” is to be found. Indeed, the word “bone” is not found anywhere in the copending claims of the `234 and `353 applications. Thus, the copending claims of the `234 and `353 applications do not “already recite the treatment of repairing bone tissue”. Hence, the alleged feature of the `234 and `353 applications relied upon in the office action for finding combination with Dunn obvious does not exist. Consequently, for at least this reason, the office action fails to provide a proper basis upon which obviousness-type double patenting can be found.

Moreover, the text of the `234 and `353 applications make clear that they relate to treatment of soft tissues. For example, the `234 and `353 applications teach that “[c]losure of an open wound requires inward migration of surrounding epithelial and subcutaneous tissue.”

(US 2001-0029956 A1, paragraph [0002], second sentence. Applicants cite to US 2001-0029956 which is the published '234 application, and which also pertains to the '353 application, since the '353 application is a continuation of the '234 application.). “In operation, a method of treating tissue damage is provided which comprises applying a negative or reduced pressure to a wound over an area sufficient to promote the migration of epithelial-and subcutaneous tissue toward the wound and for a time period sufficient to facilitate closure of the wound.” (Emphasis Added. US 2001-0029956 A1, paragraph [0012], first sentence.). Moreover, US 5,645,081, incorporated by reference in the '234 and '353 applications, teaches that “[t]he use of negative pressure provides tension on this border tissue that causes accelerated tissue migration [which] .... also causes within the wound increased formation of granulation tissue, a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that aids in healing.” (Emphasis Added. US 5,645,081, column 2, lines 51-58.).

Thus, the expectation and knowledge of one skilled in the art for successful use of reduced pressure as taught in the '234 and '353 applications is limited to treating those tissues which are able to be placed in tension in response to application of reduced pressure, namely soft tissues, such as epithelial and subcutaneous tissue. Hard tissues, such as bone, are not placed in tension in response to the application of reduced pressure like soft tissues are. For example, while the opposite ends of a soft tissue wound can be pulled together by simply using one's fingers or reduced pressure therapy, the opposite ends of a bone cavity or bone hole cannot. Consequently, one of the healing mechanisms believed to be useful for the vacuum treatment of soft tissue wounds simply does not exist for bone cavities and defects. Thus, there would have been no expectation of one skilled in the art that the application of reduced pressure to bone tissue and a bone substitute material would provide the type of effect disclosed in the '234 and '353 applications. The '234 and '353 applications do not disclose treatment of hard tissue and do not suggest such a use to the skilled reader, because it is not obvious that a device that promotes healing in soft tissue will also promote healing in a rigid material such as bone.

The '234 and '353 applications disclose soft tissue treatment using reduced pressure, but fail to disclose or suggest that the reduced pressure can have any effect whatsoever on hard tissue. Dunn on the other hand, makes no mention whatsoever of reduced pressure. Dunn

merely relates to “a surgically implantable device coated with an adjunctive polymer system... [that] can contain a drug or medicament which is released over time from the solid matrix [of the adjunctive polymer system].” (Abstract.) Thus, while Dunn does mention bone tissue, Dunn does not disclose or suggest reduced pressure. As such, Dunn fails to supply both the motivation or suggestion to (1) make the proposed combination of a reduced pressure system with hard tissue, (the teaching missing from the ‘234 and ‘353 applications) and (2) the reasonable expectation that such a combination would be successful that is also missing from the ‘234 and ‘353 applications. (Again, as pointed out above, the claims of the ‘234 and ‘353 applications do not “recite the treatment of repairing bone tissue.”)

Hence, there is no suggestion or motivation to make the proposed combination of Dunn with either of the ‘234 and ‘353 applications, and there is no reasonable expectation of success in combining the references, for at least the reasons that all the references relied upon in the rejection fail to recognize that bone tissue (and a bone substitute material) can be beneficially affected through the application of reduced pressure. Since the person of ordinary skill in the art understood that tension and tissue migration were a basic component of a successful treatment with reduced pressure, the person of ordinary skill in the art would never be motivated to make the proposed prior art combination, because hard tissue, such as bone, is not expected to undergo tension or tissue migration in response to reduced pressure. Indeed, based on the teachings of the asserted prior art, a person of ordinary skill in the art would in fact have no reasonable expectation of success. Traditionally, one skilled in the art understands that mechanical systems such as pins and fixators and distractors are required to place bone tissue under tension.

For the above reasons, Applicants respectfully submit that a combination of the ‘234 and ‘353 applications with Dunn is insufficient, at the very least because there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings, and there is no reasonable expectation of success. However, yet additional reasons exist for concluding combination of the ‘234 and ‘353 applications with Dunn is inappropriate.

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**Examiner: Philogene, P.**

In one of its aspects, the Dunn system provides a surgically implantable device coated with an adjunctive polymer system that can contain a drug or medicament which is released over time from the solid matrix. (Abstract.) Specifically, Dunn teaches that “[w]hen used near or in conjunction with bone tissue, the adjunctive polymer system preferably contains a biologically active agent to prevent infection and aid in healing.” (Column 15, lines 27-29.) Dunn further explains that the “bioactive material will be released from the matrix into the adjacent tissues...” (Column 12, lines 31-32.) Thus, Dunn discloses generic surgically implantable devices that are coated with an adjunctive polymer system that can serve as a drug delivery vehicle. In order for the adjunctive polymer system of Dunn to be effective, the drugs it provides must reach the tissues to be treated. However, modifying the device of Dunn to provide the reduced pressure appliance and method of the ‘234 and ‘353 applications over it, would render the device of Dunn less suited for its intended purpose, because the vacuum device of the ‘234 and ‘353 applications would tend to draw off the drugs supplied by the Dunn device so that the drugs would be removed from the patient resulting in a decreased chance to treat the tissues adjacent the implanted Dunn device. That is, the entire purpose of implanting the drug-delivering Dunn surgical device would be impeded, or at least rendered less effective, if Dunn were combined with the ‘234 and ‘353 applications. A person skilled in the art would realize that applying a vacuum about the device of Dunn would remove the drugs as they are released from the Dunn device, defeating its purpose. Therefore, one skilled in the art would never consider it obvious to combine the device and method of the ‘234 and ‘353 applications with that of Dunn.

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references relied on by the Examiner or by knowledge generally available to one of ordinary skill in the art, to modify such references or to combine the disclosures thereof to arrived at Applicants' claimed invention. The combined disclosures relied upon by the Examiner fail to give rise to a reasonable expectation that *applying a reduced pressure to hard tissue*, such as bone, as claimed by Applicants should even be attempted or succeed.

Accordingly, Applicants respectfully request that the provisional obviousness-type double patenting rejections of claims 1-13 over copending Application Nos. 09/026353 and 09/863,234 in view of Dunn et al. (5,717,030) be withdrawn.

**PREVIOUSLY SUBMITTED IDS's**

Applicants have not received a signed copy of the Form 1449 received by the United States Patent and Trademark Office on September 13, 2004. Applicants respectfully request a signed an initialed copy of the Form 1449 dated September 13, 2004. Also, Applicants have not received a singed copy of page 12 of the Information Disclosure Statement of September 17, 2004, and request a signed copy of page 12.

Early and favorable reconsideration is respectfully requested. The Examiner is invited to telephone the undersigned in the event that a telephone interview will advance prosecution of this application.

Respectfully submitted,

/ Niels Haun /

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